EUROPEAN COMMISSION

Directorate-General for Communications Networks, Content and Technology

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**SUMMARY OF THE MEETING**

# STAKEHOLDER MEETING ON QUALITY AND RELIABILITY OF MOBILE HEALTH APPLICATIONS
# 06TH JULY 2015, BRUSSELS

## Introduction

The meeting was organised by DG CONNECT as a follow-up to the Green Paper on mobile health and the public consultation with the aim to further discuss with the stakeholders possible future policy actions on quality and reliability of mobile health applications.

The meeting was attended by representatives from public authorities, industry, academia, patient and professional associations.

Peteris Zilgalvis, Head of Health and Wellbeing Unit, DG CONNECT summarised in the introductory presentation the results of the public consultation and the discussion that took place at the open mHealth stakeholder meeting on the 12th May in Riga, outlining the main concerns and proposed actions as regards safety and transparency aspects of lifestyle and wellbeing apps. He also outlined other initiatives that have been envisaged to provide a comprehensive response to the main challenges identified in the public consultation, in particular as regards data protection and the clarity of the legal framework.
To address the issue of legal clarity, the Commission has started preparations to develop a pro-innovation legal framework aiming to clarify the legal status of health and wellness apps as consumer products. In order to clarify the borderline between "medical" and "lifestyle and wellbeing apps" work is ongoing to review and update the MEDDEV guidelines.

Petra Leroy Cadova, from DG GROW gave an overview on the state of play and the main issues covered by the revision of the of the MEDDEV Guidance entitled "Guidelines on the qualification and classification of stand alone software used in healthcare within the regulatory framework of medical devices", e.g classification of the software based on location rather than function, including a specific reference to apps and aligning work also being carried out in the context of the IMDRF on definition of stand-alone software. Discussions are expected to continue at the next meeting of the Working Group on Software on 20 October whereby adoption is expected to take place in 2016. Furthermore, the Manual on Borderline and Classification in the Community

Regulatory Framework for Medical Devices is also a useful document with concrete examples of software and mobile applications which may or may not qualify as medical devices.

**Discussion on the standardisation**

The Commission announced the intention of facilitating the development of a European standard on quality criteria for the development of health and wellness apps, taking as a basis the publicly available specification PAS:277 recently published by the British Standards Institution (BSI).

Anne Hayes from the BSI introduced *PAS 277:2015 on Health and wellness apps – Quality criteria across the life cycle – Code of practice*. The aim of the standard, developed for the UK market, is to ensure robustness of the app development process by establishing main principles and specifying aspects that app developers would need to take into account from the outset. These aspects include for example legislative compliance, usability, measuring the outcomes, updating and maintenance of the app, sustainability and risk management. The focus very much is on ensuring that the apps are fit for purpose and meet the public needs. This requires a lot of user interaction that is a challenge, especially for small developers who do not have the appropriate structures in place.

The questions raised as part of the discussion focussed on the application of the standard, for example as regards the quality criteria, and the stakeholder involvement. It was explained that the standard was developed in close collaboration with all stakeholders, e.g workshops were organised bringing together different stakeholders and the industry participated through an open forum. The importance of engaging with the industry and payers was acknowledged to facilitate the use of the standard. A question also was raised about clinical evidence and evidence based guidelines needed for doctors to be able to recommend apps and whether the standard would be appropriate to address this issue. It was noted that the standard is focussing on the app development lifecycle and as such is not intended to standardise clinical practice.

**Discussion on the certification and guidelines**

On the certification and quality labelling the Commission explained that it intends to build on and support the existing initiatives on voluntary certification rather than set up new mechanisms at the EU level. This approach is in line with the subsidiarity principle and takes into account market access issues (no premarketing certification). There are some initiatives in different Member States and there is ambition to link apps to the electronic health records to enable more personalised care.

Silvia Gomez, from the European Federation of Nurses Associations (EFN) introduced the guidelines produced as part of the ENS4Care project on how nurses can use technology in a cost-effective way in the prevention of non-communicable diseases. One particular apps is used as an example in the guidelines to highlight issues to be considered by nurses and social workers in choosing eHealth technologies. It was emphasised that by bringing together the knowledge of different stakeholders there is potential to assess whether an app could be useful and promote its use among professionals.

Tomé Vardasca, from the Portuguese Ministry of Health Shared Services introduced the initiatives in Portugal to develop a vision paper for mHealth in Portugal. A number of

workshops have been organised with various stakeholders, including industry, healthcare professionals and patient groups to identify the main issues to be considered, e.g how to classify and evaluate mobile health apps and criteria for prescription of apps.

The Commission proposed for discussion a possible future collaboration between interested Member State public authorities, e.g to develop common assessment methodologies, to facilitate mutual recognition or to build a common platform for certified health apps. The Commission also introduced the idea of developing guidelines at the EU level for assessing validity of data for the purposes of linking apps to the electronic health records (EHR). These guidelines could be facilitated by the Commission or interested Member States. The aim would be to narrow the scope and focus efforts to public service use, i.e not to assess all apps but only those which declare the intention to be linked to the EHR. However, the scope is open to discussion and it needs to be considered what can be done at EU or Member State level and what the role of professional and patient organisations could be.

Two concrete examples emerged from the discussion illustrating different approaches to certification:

1) A certification mechanism has been set up in France by Medappcare, a start-up company established in 2012. The evaluation methodology is based on 17 evaluation criteria. So far 30 apps have been evaluated and 20 were certified. A question was raised as regards the implications of the certification, whether it leads to distinction for the market or to the integration of the app in the health care delivery and reimbursement system. It was explained that Medappcare is working also with public authorities and health insurance companies to recommend apps. Information on apps that do not get certification is not made publicly available but developers are given recommendations for improvement. It was also clarified that Medappcare assesses also clinical effectiveness and is working with the health professionals, though no clinical trials are carried out.
2) In Finland a three steps approach is used: 1) no certification – no access to public service 2) privacy and security to access public information system 3) usefulness and medical evaluation carried out by health authorities or professional associations.

In the discussion, views were expressed in support of certified apps to be used in the healthcare setting as well as developing common criteria and assessment methodologies. Following points were made by the participants more specifically:

- in the hospitals currently only certified software for pharmaceutical prescribing can be used and this should be the case also for apps. Plug and play solutions are needed based on common computer standards.
- apps related to diagnoses, therapy and screening should be classified as medical devices (e.g psychiatric, alcohol and drug addiction, diabetes apps)
- health insurance providers need to have evidence on the added value of apps in order to include these in the reimbursement schemes. Legal clarity and clarity on certification is needed.
- doctors need clinical evidence in line with the principles of evidence based medicine in order to be able to recommend apps. However, the certification process fails to assess the real clinical value of the apps as this requires medical research.

- It was questioned whether clinical evidence is relevant in this context as apps should rely on already existing clinical evidence (e.g the fact that physical activity and healthy nutrition are essential in prevention of certain chronic conditions).
- methodologies for assessing effectiveness exist but they need to be adapted and adopted in order to be useful for mHealth.
- there is a need for a more uniform approach in order to make the apps more useful for the users. This can be soft law and not heavy regulation. It is especially important for patients with long term progressing conditions (such as COPD) that they are able to choose the app that works.
- reliability of apps often depends on other devices used in combination, such as measuring devices. It would be important to make the link for assessment purposes. What is more important is the intended use of data processed by the app, based on that a graduated labelling could be applied e.g blood pressure monitor grading in UK.
- the focus should be to look at the nature of the services and not the tools/apps. Certification could be difficult and costly for SMEs and not appropriate taking into account the dynamics of app development process.
- Enforcement issues in relation to qualifying apps as medical devices based on the intended use were raised and the need to cooperate with the medical devices authorities.
- For wellness apps encouraging transparency, informing consumers and enforcing consumer protection law is important.
- More visibility should be given in the app stores to display the certification/ endorsement of the apps. This is currently missing.

**Next steps**

The stakeholders will be asked to express their interest to participate in the working group to be set up on the EU guidelines for assessing validity of data for the purposes of linking health apps to the electronic health records.

The aim of this group would be to develop guidelines on the criteria that could be used by public authorities, health care providers, professional and patient associations, developers and other relevant bodies to assess the validity and reliability of the data collected and processed by health apps with the purpose of linking the data to the electronic health records. A drafting team would be set-up from the members of the Working Group. The Commission would facilitate the process.